


# PATENT COOPERATION TREATY

# PCT

REC'D 17 FEB 2005

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY PCT (Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference REP07750WO		<b>FOR FURTHER ACTION</b>		See Form PCT/PEA/416
International application No. PCT/GB2004/000078		International filing date (day/month/year) 12.01.2004	Priority date (day/month/year) 14.01.2003	
International Patent Classification (IPC) or national classification and IPC A61F2/00				
Applicant BARKER, Stephen G. E.				
<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 7 sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> sent to the applicant and to the International Bureau) a total of sheets, as follows:</p> <p><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input type="checkbox"/> (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>				
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the opinion</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input checked="" type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application</p>				
Date of submission of the demand  16.08.2004		Date of completion of this report  16.02.2005		
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465		Authorized Officer  Newman, B  Telephone No. +49 89 2399-6035		



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**Box No. I Basis of the report**

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1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)
2. With regard to the **elements\*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

**Description, Pages**

1-5 as originally filed

**Claims, Numbers**

1-11 received on 16.11.2004 with letter of 15.11.2004

**Drawings, Sheets**

1/2-2/2 as originally filed

- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing *(specify)*:
- ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/figs
- ☐ the sequence listing *(specify)*:
- ☐ any table(s) related to sequence listing *(specify)*:

\* If item 4 applies, some or all of these sheets may be marked "superseded."

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**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

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1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 11

because:

☒ the said international application, or the said claims Nos. 11 relate to the following subject matter which does not require an international preliminary examination (specify):

**see separate sheet**

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.

☐ See separate sheet for further details

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**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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1. Statement

Novelty (N)	Yes: Claims	1 - 10
	No: Claims	
Inventive step (IS)	Yes: Claims	1 - 10
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1 - 10
	No: Claims	

2. Citations and explanations (Rule 70.7):

**see separate sheet**

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**Box No. VI Certain documents cited**

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1. Certain published documents (Rule 70.10)

and /or

2. Non-written disclosures (Rule 70.9)

**see separate sheet**

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**Box No. VIII Certain observations on the international application**

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The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

**see separate sheet**

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**Re Item III**

**Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. According to Rule 67.1 PCT the International Preliminary Examination Authority, in the present case, the EPO, is not required to carry out an international preliminary examination if the subject-matter of the international application relates to methods of treatment of the human or animal body by surgery or therapy as well as diagnostic methods. Claim 11 refers to use of an implantable prosthesis for the treatment of openings as are found with hernia defects. This use clearly involves a surgical step.

**Re Item V**

**Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

2. Reference is made to the following documents:

D1: FR 2810536 (Cousin Biotech)

D2: WO 03/002029 (Ethicon, Inc.)

- 3.1 The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and shows (the references in parentheses applying to this document):

An implantable prosthesis for the repair of muscle wall defects (abstract), the prosthesis comprising a flexible plug of a surgically compatible mesh material (page 5, lines 28 - 30), wherein the plug has an elongate prismatic shape with three or more projecting longitudinal lobes or ridges (figure 2).

Furthermore these features are also disclosed in document D2 (abstract; figure 8; page 6, line 23 - page 7, line 9).

The subject-matter of claim 1 differs from this known prosthesis in that the lobes or ridges have apices which are joined by linear sides.

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).

- 3.2 The problem to be solved by the present invention may be regarded as that of stiffening a prosthesis for the use in muscle wall repair, thus improving its

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performance. The feature of joining the apices of the lobes or ridges of a prosthesis is not disclosed in the prior art documents, either alone or in combination and there is no indication suggesting the use of this feature.

The solution to the problem proposed in claim 1 of the present application is considered as involving an inventive step (Article 33(3) PCT).

4. Claims 2 - 10 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

**Re Item VI**

**Certain documents cited**

5. The applicant should also be aware of the following:

Certain published documents (Rule 70.10)

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 03/011181	13.02.2003	31.07.2002	3.08.2001

**Re Item VIII**

**Certain observations on the international application**

- 6.1 The description is not in conformity with the claims. Statements such as "the plug may comprise a projecting lobe" (page 1, line 25 - page 2, line 1) imply that these features are not necessary and lead to doubt concerning the matter for which protection is sought, thereby rendering the claims unclear, Article 6 PCT.
- 6.2 Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.
- 6.3 Independent claim 1 is not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule

6.3(b)(ii) PCT).

In the present case, the following features are known in combination from the document D1 and belong in the preamble of such a claim:

An implantable prosthesis for the repair of muscle wall defects, the prosthesis comprising a flexible plug of a surgically compatible mesh material, wherein the plug has an elongate prismatic shape with three or more projecting longitudinal lobes or ridges.

6.4 The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

CLAIMS

1. An implantable prosthesis for the repair of muscle wall defects, the prosthesis comprising a flexible plug of a surgically compatible mesh material, wherein the plug has an elongate, prismatic shape with a profile having three or more projecting longitudinal lobes or ridges whose apices are joined by linear sides.
2. An implantable prosthesis in accordance with claim 1, which has a generally triangular cross-section.
3. An implantable prosthesis in accordance with claim 1 or claim 2, which comprises internal longitudinal webs that support the profile of the mesh.
4. An implantable prosthesis in accordance with claim 3, wherein the webs are an integral part of the mesh configured by folding or formed by separate parts bonded to the inner surface of the outer profile.
5. An implantable prosthesis in accordance with any preceding claim, formed by a plurality of individual units connected in a longitudinal side-by-side relationship.
6. An implantable prosthesis in accordance with any preceding claim, wherein each said unit has a prismatic profile.
7. An implantable prosthesis in accordance with any preceding claim, which comprises three or more elongate sub-units, each of a triangular profile, connected together.
8. An implantable prosthesis in accordance with any preceding claim, wherein the mesh is pleated circumferentially or longitudinally, to provide a degree of flexibility and compressibility, to facilitate placement into a defect comprising a hernia.
9. An implantable prosthesis in accordance with any preceding claim, modified whereby the plug has an open side in the form of a triangular profiled trough, the shape being maintained by an internal support formed by mesh material.



10. An implantable prosthesis in accordance with any preceding claim, wherein the mesh material comprises polypropylene with jointing, if required, achieved by heat-sealing.

- 5 11. Use of an implantable prosthesis in accordance with any preceding claim, for the treatment of elongate or rectangular openings such as are found with inguinal hernia defects.